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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/524,113	03/13/00	PATEL J	6475.US.02

EXAMINER	
BAHAR, M	
ART UNIT	**PAPER NUMBER**
1617	14

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HM12/0921

DATE MAILED: 09/21/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary	Application No. 09/524,113	Applicant(s) PATEL ET AL.	
	Examiner Mojdeh Bahar	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 July 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's response to the first office action of February 27, 2001, submitted July 11, 2001 (Paper No. 12) is acknowledged.

Applicant's remarks and amendments submitted July 11, 2001 in Paper No. 12 are persuasive to remove the rejection under 35 U.S.C. sections 101, 102 and112 in the previous office action. Claims 1-12 are herein examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites the limitation "said lipid-regulating agent" in lines 1 and 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krueger et al., (EP 0031603) in view of Suzuki et al., (EP 0700678) and The Merck Index. Note that both European Patents were submitted in the Information Disclosure Statement of September 1, 2000.

Krueger et al., (EP 0031603) teaches a composition for improved absorption of drugs which are poorly water soluble and poorly absorbed, abstract. More specifically, Krueger et al., (EP 0031603) teaches an emulsion composition or delivery system comprising a lipid regulating agent, sesame oil and an emulsifier, which is a sorbitan fatty acid derivative, polysorbate 80, page 1, lines 17-22 and page 15, lines 25-34. Krueger et al., (EP 0031603) also teaches that clofibrate is a hypocholesterolemic or "lipid regulating" agent, page 4, line 3. Moreover, Kreuger teaches the use of pharmaceutically acceptable oils broadly in his lipid-regulating emulsion composition, page 4 line 33-page 5, line 2. Finally, Kreuger teaches that the resulting suspension can be administered orally, in capsule form, page 5, lines 26-30.

Krueger et al., (EP 0031603) does not teach statins as lipid-regulating agents. Neither does it teach the employment of a co-solvent in the emulsion, nor does it teach the employment of atorvastatin particularly in the composition therein.

Suzuki et al., (EP 0700678) teaches the employment of antihyperlipidemic agents in general, and the employment of the particular lipid regulating agents pravastatin and derivatives thereof, in an oil and water emulsion composition, page 4, line 58. Suzuki et al. also teaches the employment of a hexane-ethanol mixed solvent in the lipid emulsion composition, page 17, line 31.

It would have been obvious for one of ordinary skill in the art at the time the invention was made to use any of the statins known to be antihyperlipidemic agent, e.g. simvastatin,

pravastatin and atorvastatin (see The Merck Index, page 146) in the Kreuger emulsion composition. It would have also been obvious to substitute any oil of vegetable origin for sesame oil in the emulsion composition of Kreuger. Furthermore, it would have been obvious to employ a co-solvent in the oil-in-water emulsion composition of Kreuger.

One of ordinary skill in the art would have been motivated to employ statins in the lipid regulating agent emulsion composition of Kreuger because statins are known lipid-regulating agents, and are thus expected to be useful similar to as clofibrate, p-hexadecylaminobenzoic acid sodium salt, or other lipid-regulating agents in Kreuger's composition. Similarly, one of ordinary skill in the art would have reasonably expected any pharmaceutically acceptable oil, including soya bean oil, to be similarly useful in the oil-in-water emulsion composition of Kreuger, see page 4, line 33-page 5 line 20 therein. Finally, the skilled artisan would have been motivated to use a co-solvent that does not effect the properties of the emulsion in order to improve the solubility as well as absorption of the lipid regulating agent in the host.

Applicant's arguments that Kreuger does not teach a solution, neither does it teach a fibrate have been considered but are not persuasive to remove the obviousness rejection. Applicant argues that the claimed invention is directed to a "solution of a fibrate, an oil and one or more emulsifiers." The final composition in the claimed invention is indeed an emulsion, see particularly claim 1, lines 7-8. However, the Krueger composition comprises a lipid regulating agent, sesame oil and an emulsifier, which is a sorbitan fatty acid derivative, polysorbate 80, page 1, lines 17-22 and page 15, lines 25-34. Krueger et al., (EP 0031603) also teaches that clofibrate is a hypocholesterolemic or "lipid regulating" agent, page 4, line 3.

Applicants arguments regarding Suzuki have also been considered but are not persuasive. Applicant argues that Suzuki's composition contains citric acid and amino acids, none of which are present in the claimed invention. Note that the claim language uses the open transition "a composition **comprising**" which does not preclude the presence of agents other than those claimed in the composition.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 on Monday, Tuesday, Thursday and Friday from 8:30 a.m. to 6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar
Patent Examiner
September 19, 2001

RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200